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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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James L. Hartley

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/517,466	Applicant(s) HARTLEY ET AL.	
	Examiner Diana B. Johannsen	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>0209</u> . | 6) <input type="checkbox"/> Other: _____ |

FINAL ACTION

1. This action is responsive to the Amendment and Reply filed February 4, 2009.

Claims 39-41 have been amended. Claims 39-49 remain pending and under consideration. Applicant's amendments and arguments have been thoroughly reviewed, but are moot in view of the new grounds of rejection set forth below. Any rejections and/or objections not reiterated in this action have been withdrawn. **This action is FINAL.**

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

3. The information disclosure statement filed February 4, 2009 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed.

Specifically, cite numbers B19-B22 and B24 have not been considered because copies of the documents have not been provided (if applicant wishes to have the provided search reports corresponding to these documents considered, then the search reports themselves should be cited).

Regarding cite number B1, the provided English abstract has been considered and the correct date has been provided for the reference.

Additionally, cites A1-A3 and A5-A7 have not been considered because applicant has not provided complete citations for these documents. Applicant is also reminded

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that for any application not stored in the image file wrapper system, copies of the required material must be provided (see MPEP 609.04(a) and C7 CFR 1.98).

Cite numbers C1-C4 and C66-C68 were not considered because the dates provided in the citations do not match any date that appears in documents otherwise including information corresponding to these citations (e.g., applicant has provided search reports including corresponding application numbers, but the mailing dates cited on the IDS do not actually appear in the material cited).

Cite numbers C18, C27-C29, C31, C33, C42, C55, C59, and C65 were not considered because the documents corresponding to the citations are not complete (specifically, each of these documents appears to be a portion of a response, rather than a complete "Response" including all sections and a signature). If applicant wishes for only portions of these documents to be considered, those portions should be completely and accurately cited.

Cite numbers C12-C13, C17, C39, C41, C50, C54, C57-C58, and C63-C64 were not considered because no copy of a document corresponding to these citations could be identified. It is noted that applicant did provide several incomplete/partial documents lacking dates; however, those documents could not be considered because they lacked a date that would allow the documents to be identified as corresponding to a particular citation on the IDS (additionally, the majority of these undated documents were also incomplete).

Cite number C79 was not considered because a copy of the document was not provided.

Claim Rejections - 35 USC § 112, first paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY

APPLICANT'S AMENDMENTS:

5. Claims 39-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

First, independent claim 39 (from which claims 40-49 depend) has been amended such that it is now drawn to an "isolated nucleic acid molecule comprising a lambdoid *att* recombination site wherein a sequence of a seven base pair overlap region within a fifteen base pair core region is ATTATAC". While applicant's specification clearly discloses lambda *att* recombination sites wherein the 7 base pair overlap region with the 7 base pair core region of the recombination site is ATTATAC, basis for **lambdoid** recombination sites of this type is lacking. It is noted that the term lambdoid is sometimes used in the prior art to refer to a group of "lambda-like" phage of which lambda is a member (see, e.g., the prior art as exemplified by US 6,884,612 B2 (filed 6 May 2007); col 9, lines 1-11); alternatively, the term may be used in the art to refer to "natural relatives" of lambda, such that lambda itself is not considered "lambdoid" (see,

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e.g., Campbell, *Annu. Rev. Microbiol.* 48:193-222 (1994); page 193). A review of the instant specification (including the particular sections cited in the Reply as supporting the amendments), as well as of the applications of which the instant application claims benefit and the materials incorporated by reference at page 59, does not reveal support for a genus of "lambdoid" recombination sites having the structure set forth in the claims. Rather, the application discloses mutated versions of **lambda** recombination sites (particularly, attB, attP, attL, and attR) having this sequence/structure (see, e.g., pages 59-61). It is further noted that the specification does not appear to even disclose or define the term "lambdoid". Accordingly, applicant's amendment to claim 39 introduces new matter.

Additionally, the claims as written embrace lambdoid/lambda *att* recombination sites in which any "sequence of a seven base pair overlap region within a fifteen base pair core region is ATTATAC". However, the specification discloses only lambda recombination sites in which the seven base pair overlap region within the fifteen base pair core region is ATTATAC (see, e.g. the discussion at pages 59-60 referenced by applicant in supporting the amendment). While the language of the amended claims suggests that there are, e.g., multiple types of seven base pair overlap regions and multiple types of "fifteen base pair core regions" in lambda recombination sites, the originally filed specification refers to and discloses only the particular, known overlap and core regions as being mutated in such a way that a particular structure possessing the ATTATAC sequence is produced. Accordingly, applicant's amendments also

introduce new matter by embracing such a broader genus of molecules that was not originally disclosed.

Claim Rejections - 35 USC § 112, second paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 39-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY
APPLICANT'S AMENDMENTS:**

Claims 39-49 are indefinite over the use of the term "lambdoid" in claim 39. Neither the specification nor the prior art provides a clear definition of this term. It is again noted that the term lambdoid is sometimes used in the prior art to refer to a group of "lambda-like" phage of which lambda is a member (see, e.g., the prior art as exemplified by US 6,884,612 B2 (filed 6 May 2007); col 9, lines 1-11); alternatively, the term may be used in the art to refer to "natural relatives" of lambda, such that lambda itself is not considered "lambdoid" (see, e.g., Campbell, Annu. Rev. Microbiol. 48:193-222 (1994); page 193). It is not clear whether applicant's use of the term is meant to incorporate one of these prior art meanings (and if so, which one); or whether, e.g., given the lack of disclosure or discussion in the specification with regard to the term "lambdoid", this term may be intended to have some other meaning within the context of the claimed invention. As it would not be clear to one of skill in the art what types of

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structures are/are not embraced by the instant claims (and therefore what structures would/would not infringe the claims), the claims are indefinite.

Claim 40 is also indefinite because it is not clear how it further limits claim 39, from which it depends. The claim is directed to the "isolated nucleic acid molecule of claim 39, which comprises two or more lambdoid *att* recombination sites". However, claim 39 does not merely require a molecule comprising any lambdoid *att* recombination site; rather, the claim requires a site having the particular structure including ATTATAC. The wording of claim 40 does not clearly indicate the inclusion of this entire structure of claim 39, as is necessary for a proper dependent claim. Further, it is additionally not clear whether claim 40 is directed to a molecule including two sites having the structure indicated in claim 39, to a molecule including that site plus two additional "lambdoid *att* recombination sites," one of each type of recombination site, etc. Accordingly, as the types of structures embraced by claim 40 is not clear, the claim is indefinite.

It is noted that the new rejections under 35 USC 112, first and second paragraphs set forth above could be overcome by amending claims 39-40 as follows:

39. An isolated nucleic acid molecule comprising a lambda *att* recombination site wherein the sequence of the seven base pair overlap region within the fifteen base pair core region of the recombination site is ATTATAC.

40. The isolated nucleic acid molecule of claim 39, which comprises two or more copies of said lambda *att* recombination site.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diana B. Johannsen/
Primary Examiner, Art Unit 1634